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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,109	06/12/2001	Jacques Paris	GEI-073	6348

20311 7590 12/28/2001

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600 THIRD AVENUE
NEW YORK, NY 10016

EXAMINER

STILLER, KARL J

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 12/28/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/423,109

Applicant(s)

PARIS ET AL.

Examiner

Karl Stiller

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Individual estrogenic compounds and individual progestative compounds derived from 19-norprogesterone.

Applicant is required, in reply to this action, to elect a single species, which is a single disclosed estrogenic compound (e.g., 17 β -estradiol, estrone sodium sulfate, equilin sodium sulfate, equilenin, etc.) and a single disclosed progestative compound derived from 19-norprogesterone (e.g., ethynodiol diacetate, quingestanol acetate, cyproterone acetate, etc.), to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

All claims are generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: A common central core to the estrogenic compounds is lacking; i.e. a **significant** structural element is not shared by the compounds. The only structural elements common to the estrogenic compounds herein are the A and D rings and a methyl group at position 18 of otherwise dissimilar cyclopentanohydrophenanthrene ring systems. For example, 17 β -estradiol has an –OH group attached at the 3 and 17 positions, whereas the conjugated equine estrogens, estrone sodium sulfate and equilin sodium sulfate have sodium sulfate attached at the 3 position and =O attached at the 17 position. The other conjugated equine estrogen, equilenin, has –OH attached at the 3 position and =O attached at the 17 position. Equilenin also has a double bond between the 6 and 7 position and another between the 8 and 9 position, whereas estrone sodium sulfate, equilin sodium sulfate and estradiol lack this feature. Equilin sodium sulfate has a double bond between the 7 and 8 positions, which is a feature not shared by the other estrogens above.

Therefore, the individual estrogenic compounds herein are not seen to share a significant structural element.

A common central core to the progestative compounds derived from 19-norprogesterone is also lacking; i.e. a **significant** structural element is not shared by the compounds. The only structural elements common to the progestative compounds derived from 19-norprogesterone herein are the C and D rings of otherwise dissimilar cyclopentanohydrophenanthrene ring systems. For example, ethynodiol diacetate has -OC(=O)CH_3 attached at the 3 position, whereas cyproterone acetate has =O and quingestanol acetate has -O-(cyclopentane) . Ethynodiol diacetate also has -OC(=O)CH_3 and $\text{-C}\equiv\text{CH}$ attached at the 17 position, whereas cyproterone acetate and quingestanol acetate only have -OC(=O)CH_3 . Ethynodiol diacetate also has a double bond between the 4 and 5 positions, whereas cyproterone acetate has an additional double bond between the 6 and 7 positions and has -Cl attached at the 6 position. Quingestanol acetate has a double bond between the 3 and 4 positions and another between the 5 and 6 positions.

Therefore, the individual progestative compounds derived from 19-norprogesterone herein are not seen to share a significant structural element.

A telephone call was made to Charles A. Muserlian on December 19, 2001 to request an oral election to the above restriction requirement, but did not result in an election being made.

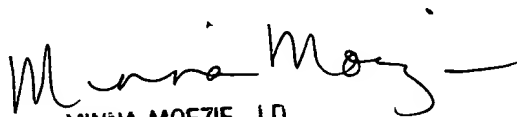
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl Stiller whose telephone number is 703-306-3219. The examiner can normally be reached Monday through Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached at 703-308-4612. The fax phone number for the organization where this application or proceeding is assigned is 703-308-4556 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Stiller: ks
December 20, 2001


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600